UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/567,470	11/30/2006	Patrick L. Iversen	50450-8055.US00	4986

79975 7590 08/11/2009

King & Spalding LLP
P.O. Box 889
Belmont, CA 94002-0889

EXAMINER	
ANGELL, JON E	

ART UNIT	PAPER NUMBER
1635	

MAIL DATE	DELIVERY MODE
08/11/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/567,470	IVERSEN, PATRICK L.	
	Examiner	Art Unit	
	J. E. Angell	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☒ Claim(s) *21* is/are objected to.

8)☒ Claim(s) *1-20 and 22-29* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-29 are currently pending.

Claim Objection

Claim 21 is objected to because it is drawn to "The compound of claim 14"; however, claim 14 is drawn to a method, not a compound. As such claim 21 is unclear and appropriate correction is required. Accordingly claim 21 has not been included in Group at this time, but will be rejoined with the appropriate group upon correction of the problem.

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-13, drawn to an oligonucleotide analog compound. Election of this group requires the further election of a single viral family from claim 1; and a single sequence (i.e., SEQ ID NO) from claims 7-12, as explained below.

Group II, claim(s) 14-20, 22-26, drawn to a method of inhibiting replication of an RNA virus using an oligonucleotide analog compound. Election of this group requires the further election of a single viral family from claim 14; and a single sequence (i.e., SEQ ID NO) from claims 21-26, as explained below.

Group III, claim(s) 27-29, drawn to a method of confirming the presence of an effective interaction between a virus and an uncharged morpholino sense oligonucleotide analog compound. Election of this group requires the further election of a single viral family from claim 27 and 29, as explained below.

The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: since the broadest claim (claim 1) does not provide a special technical feature over the prior art (see Stein et al., Anderson et al., and Banerjee et al., cited as references in the International Search Report (ISR)). PCT Rule 13.2 states "The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes ***over the prior art***." (Emphasis added). Since claim 1 does not make a contribution over the prior art as indicated in the ISR, this claim provides no special technical feature over the prior art, and unity of invention does not exist.

Restriction to a single viral family and sequence:

Should applicant elect to prosecute any of Groups I–III, these Groups are each subject to further restriction as follows.

Pursuant to 35 U.S.C. 121 and 37 C.F.R. 1.141, the virus families recited in claims 1, 14, 27 and 29; nucleic acid sequences (SEQ ID NO) recited in claims 7-12, and 21-26 are subject to restriction since they are not considered to be a proper genus/Markush and thus do not have unity of invention. See MPEP 803.02 - PRACTICE RE MARKUSH-TYPE CLAIMS - If the members of the Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the examiner must examine all the members of the Markush group in the claim on the merits, even though they are directed to independent and distinct inventions. In such a case, the examiner will not follow the procedure described below and will not require restriction. Since the decisions in *In re Weber*, 580 F.2d 455, 198 USPQ 328 (CCPA 1978) and *In re Haas*, 580 F.2d 461, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention. *In re Harnish*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984).

Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility.

The instant claims specifically claim oligonucleotides and methods of using oligonucleotides, directed to or comprising the positive RNA strand of an RNA virus from any one of 6 different families of RNA viruses. Although the viruses are related in that they all have

positive sense RNA genomes, the different families may have different genomic sequences, requiring structurally distinct antisense oligonucleotide compounds.

If it is Applicants' contention that the same oligonucleotide compounds can be used to target the same sequence(s) in each of the viral families, or that only obvious variations in the structures of the oligonucleotide compounds would be required to target, inhibit, and detect any virus from any of the families now recited, Applicants should so state on the record..

It is the Examiner's position that the products and instantly claimed methods directed to the 6 different virus families would require structurally and functionally distinct oligonucleotide compounds. Accordingly, the claimed oligonucleotide compounds, and therefore methods for use thereof, do not share a common utility, and a substantial structural feature disclosed as being essential to that utility.

Thus, the Markush/genus of virus families in the instant claims are not considered to constitute proper genera, and are therefore subject to restriction.

Furthermore, a search of more than one (1) of the oligonucleotides and/or methods recited in the instant claims presents an undue burden on the Patent and Trademark Office because the searches are non-overlapping and non-coextensive. In view of the foregoing, one (1) virus family is considered to be a reasonable number of families for examination.

Accordingly, applicants are required to elect one virus family from each of the instant claims for prosecution on the merits with the elected group. Note that this is not a species election.

In the event of rejoinder of product and process claims, applicants are reminded that the process claims identified above depending from the product claims identified above must recite the same virus family to remain consonant with this restriction requirement.

Similar reasoning applies the group of sequences (SEQ ID NOs) recited in claims 7-12, and 21-26, which do not share a substantial structural feature essential to their utility. Each sequence is unique and non-overlapping, requiring separate searches and considerations of the prior art literature. As each sequence is considered in the context of the invention as a whole, each invention thereof comprises mutually exclusive characteristics, thus there is no unity of invention between the claimed sequences.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

2. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. E. Angell whose telephone number is 571-272-0756. The examiner can normally be reached on Monday-Thursday 7:00 a.m.-5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Douglas Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. E. Angell/
Primary Examiner, Art Unit 1635